

PSJ3
Exhibit 348

From: Ducca, Anita <aducca@hda.org>
Sent: Thursday, October 23, 2014 8:40 PM
To: Tuszynski, Allison
Cc: Kelly, Patrick
Subject: RE: HDMA Monthly Officers Conference Call

Allison, looks great and thanks. Patrick, I think we're done (no pun intended).

From: Tuszynski, Allison
Sent: Thursday, October 23, 2014 4:10 PM
To: Ducca, Anita
Cc: Kelly, Patrick
Subject: Re: HDMA Monthly Officers Conference Call

Anita and Patrick,

See below including the GAO and OSHA updates.

Thanks,

Allison

From: <Ducca>, Anita Ducca <aducca@hdmanet.org>
Date: Thursday, October 23, 2014 at 2:35 PM
To: Allison Tuszynski <atuszynski@hdmanet.org>
Cc: Patrick Kelly <pkelly@hdmanet.org>
Subject: FW: HDMA Monthly Officers Conference Call

Allison, I did a quick summary for Patrick of Regulatory issues for the officers' call. (See Anne J's e-mail below.) Could you review and add in on the GAO discussion under the first group, the OSHA one and anything else you see that you think needs editing or if I've left out anything:

DEA/controlled substances

The Regulatory Affairs Committee is evaluating the DEA disposal rule's impact. Remember, it's not just a voluntary "take back" rule, it also governs disposal of any controlled substance. For example, the vague, potentially very strict requirements for timing of disposal of returned products could have longer term impacts on obtaining credit for certain returned products. Stay tuned.

We're still waiting to see if there will be shortages of hydrocodone combination products, but even if there are, our hands are tied and per our Board meeting HDMA has not been weighing in on this rule.

We (Allison and Elizabeth) participated in a GAO-requested confidential discussion of DEA issues as part of GAO's requests for information regarding a report on DEA that they're preparing. The group that met with GAO included HDMA, one HDMA member, several manufacturers, and two chain drug stores. Participants explained concerns about the lack of DEA clarification, continued discrepancies between DEA HQ and field offices, along with indifference to industry concerns and unwillingness to meet with stakeholders. When asked, GAO indicated the report would be completed approximately late 2015.

Traceability/DSCSA

Staff are putting in tremendous efforts to aid in interpreting confusing DSCSA requirements, establish HDMA guidelines, and interact with FDA. The most intense effort recently was the meeting we had with FDA (Sept. 22) on the Transaction Scenarios and the follow-up heavy duty legal analysis for why our interpretation of the data required for exclusive distributors and direct purchase repackagers makes sense, and why the lot number didn't need to be passed. The meeting was telling for how little the FDA understood the supply chain, the ASN and even how little they understood the DSCSA. The meeting was also useful for clarifying for FDA that if they made major changes in guidances at this late date, they'll significantly impact our ability to comply by 1/1/15.

Other recent FDA involvement includes:

On Sept. 19, we sent FDA recommendations for how they should draft the state standards for wholesale distributor licensure. We're preparing a separate submission on integrating 3PL licensure into their standards.

We're currently preparing comments on FDA's draft guidance on state preemption. FDA's draft emphasizes that there's a "floor" but leaves the "ceiling" wide open, so we're trying to see what legal opportunities there are to lower the ceiling. (comments due Dec. 8)

Clarifying what to do if a trading partner is legitimate, but wasn't included in the DSCSA's definition of "authorized" (After 1/1/15, no one can business with anyone else who is not "authorized").

IR is beefing up the ASN with examples and how to handle "exceptions" (e.g., a mfr ships 100 units but only sends ASN TI/TH/TS data for 50 of them)

We're planning on further educational efforts on multiple fronts, e.g., a letter and educational webinars for other trade associations, the Traceability Seminar, etc.

FDA

Other than DSCSA, FDA has been relatively quiet, although there was an interesting event when FDA sent us a letter that attempted to help out the anticipated shortages of hydrocodone resulting from DEA's rule. Except they made it worse. They thought distributors could put stickers on the bottles saying "C-II" to meet the label requirement and they stated that manufactures may not do so. We had to explain that wholesalers don't put stickers on the bottles, only manufacturers do that. By preventing manufacturers from doing so, they worsened the problem they were attempting to help.

We're reviewing a REMS report, but it's not likely to impact us much. *(Patrick, don't know if we want to include this since its relatively small potatoes, but thought I'd add it.)*

(Patrick, DOT and OSHA may be too in the weeds for these guys but I'll include in case you think it should go.)

DOT

We're looking at a new DOT rule on reverse logistics. It is intended to help simplify reverse logistics, but in some areas, it may make it worse, so we're preparing comments to let them know. (Due Nov. 10)

OSHA (Allison, could you add in a bullet on the OSHA letter we signed onto)

- The Coalition for Workplace Safety requested HDMA's signature on a comment letter to OSHA requesting that OSHA withdraw their supplemental proposed rule Tracking Workplace Injuries and Illnesses. HDMA signed on to a previous CWS comment letter to the original proposed rule also requesting that OSHA withdraw the proposed rule due to several concerns including the potential for workplace injury reports to be published online. HDMA agreed to sign on to the second comment letter.

That's what I have but pls feel free to add more if there is anything else.

Anita

From: Johnson, Anne
Sent: Thursday, October 23, 2014 10:44 AM
To: Senior Management Team
Subject: HDMA Monthly Officers Conference Call

Good morning,
John Gray has his next monthly officers conference call with the chairman on Wednesday, October 29.

Please send him any industry and association updates you have by Tuesday, October 28 at 3:00 pm.

Thanks,
Anne

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